UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. RENÉE MARIE BUMB**
THIS DOCUMENT RELATES TO: *Roberts v. Zhejiang Huahai Pharmaceutical Co. Ltd.,* Case No. 1:20-cv-00946-RMB-SAK	

PLAINTIFFS' BRIEF IN SUPPORT OF DAUBERT MOTION TO EXCLUDE DEFENSE EXPERT NADMIN MAHMUD M.D., M.S., M.P.H., M.S.C.E

NIGH GOLDENBERG RASO & VAUGHN, PLLC
Attorneys for Plaintiffs
14 Ridge Square NW
Third Floor
Washington, D.C. 20016
Tel: 202-792-7927
Fax: 202-792-7927

On the Brief:
C. Brett Vaughn RN, BSN, JD
Ashleigh Raso, Esq.
Kathryn Avila, Esq.
Stephanie Iken, Esq.

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INTRODUCTION

Plaintiffs respectfully move to exclude the testimony of defense's expert hepatologist, Nadim Mahmud, M.D., M.S., M.P.H., M.S.C.E.

In April of 2016, Mr. Roberts underwent multiple imaging studies of his liver due to a fatty liver. In September of 2016, Mr. Roberts filled his first prescription of NDMA-contaminated valsartan-HCTZ 320-25mg. Then in August of 2018, imaging revealed multiple spots of liver cancer (hepatocellular carcinoma – HCC) greater than 5cm in diameter. Despite all evidence to the contrary, Defendant has decided to defend this case by concluding that Mr. Roberts must have had liver cancer prior to ingesting NDMA-contaminated valsartan. All of Dr. Mahmud's opinions are given in an attempt to provide support for that predetermined conclusion.

Dr. Mahmud offers a series of speculative, conclusion-driven opinions that fail to meet the reliability standards required under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and Federal Rule of Evidence 702. Dr. Mahmud's opinions rest on flawed assumptions and unreliable methodologies, including: diagnosing Mr. Roberts with cirrhosis based on an inappropriately applied FIB-4 score which Dr. Mahmud calculated using an online tool that applied a formula Dr. Mahmud did not fully understand; Mr. Roberts being diagnosed with NASH (nonalcoholic steatohepatitis) despite the absence of a biopsy or clinical record; and an unspported and unwavering belief that Mr. Roberts' cancer must have

predated his first dose of NDMA-contaminated valsartan. Dr. Mahmud also failed to consider, much less rule out, alternative causes of what Dr. Mahmud considered key findings to support his opinion and application of a FIB-4 score to Mr. Roberts. In deposition, Dr. Mahmud speculated that Mr. Roberts' alleged cirrhosis would *protect* Mr. Roberts from NDMA's carcinogenic effects, a claim directly contradicted by published guidance from the U.S. Department of Health and Human Services. Because Dr. Mahmud's opinions are not grounded in fact and are not the product of reliable methodologies, his testimony should be excluded.

APPLICABLE LAW

Rule 702 and *Daubert* Standards

Expert testimony is admissible only if it is both reliable and relevant, as required by Federal Rule of Evidence 702. Under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the trial court serves a "gatekeeping" function to ensure that expert testimony is "not only relevant, but reliable." *Id.* at 589. The Third Circuit has emphasized that *Daubert*'s reliability requirement applies to both the methodology employed by the expert and the manner in which that methodology is applied. See *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 800 (3d Cir. 2017) (affirming exclusion of expert who "failed to consistently apply the scientific methods [he] articulate[d]" and "inconsistently applied methods and standards to the data so as to support [his] a priori opinion").

Courts must ensure "that the testimony given to the jury is reliable and will be more informative than confusing." *Id.*

In assessing whether an expert's testimony is reliable, courts in this Circuit apply the factors set forth in *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994), which include: (1) whether the methodology can be tested; (2) whether it has been subject to peer review; (3) the known or potential error rate; (4) the existence and maintenance of standards; and (5) whether the methodology is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put. See *id.* at 742 n.8. *Paoli* also recognizes that a court must exclude an expert's testimony if *any step* in the expert's reasoning or methodology renders the analysis unreliable. *Id.* at 745. Thus, even where an expert purports to use an accepted methodology, a court must exclude the opinion if the methodology is applied improperly or inconsistently. See *Id.* at 742–45.

This requirement of intellectual rigor is especially critical where the expert purports to rely on experience rather than empirical data. As the Third Circuit has explained, "[t]he expert must employ in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Elcock v. Kmart Corp.*, 233 F.3d 734, 746 (3d Cir. 2000) (quoting *Kumho Tire Co. v.*

Carmichael, 526 U.S. 137, 152 (1990)). An expert who departs from the norms of their discipline in litigation cannot offer admissible opinions. For example, in *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 Supp. 2d 584 (D.N.J. 2002), aff'd, 68 F. App'x 356 (3d Cir. 2003), the court excluded expert testimony where the expert's conclusions were not the result of research conducted independent of litigation and the expert failed to adequately account for alternative explanations. The court emphasized that unjustified extrapolation from accepted premises to unsupported conclusions is a hallmark of unreliable testimony. *Id.* at 594–95.

FRCP 26(a)(2)

Federal Rule of Civil Procedure 26(a)(2) governs the disclosure of expert testimony, including the specific requirements for expert reports. Under this rule, "[t]he report must contain: (i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them …." Fed. R. Civ. P. 26(a)(2)(B)(i) & (ii). Failure to comply with these requirements provides an independent ground for excluding the expert's testimony. As the Seventh Circuit has explained, "[t]he consequence of non-compliance with Rule 26(a)(2)(B) is exclusion of an expert's testimony[.]" *Meyers v. N'l R.R. Passenger Corp. (Amtrak)*, 619 F.3d 729, 734 (7th Cir. 2010) (internal quotations and citations omitted).

ARGUMENT

I. Dr. Mahmud Relies on Dr. Chernyak's Radiological Opinions and Lacks the Necessary Expertise to Give Such Radiological Opinions Himself

Dr. Mahmud repeatedly relies on and defers to Dr. Victoria Chernyak's (defense's expert radiologist) radiological interpretations in forming key opinions regarding the origin, timeline, and classification of Mr. Roberts' liver observations.[1] Dr. Mahmud concedes that he is not a diagnostic radiologist and did not independently verify Dr. Chernyak's opinions that are a key basis to his opinion, including the LI-RADS 3 classification at the core of Dr. Mahmud's cancer progression timeline. Dr. Mahmud testified, "I'm relying a lot on Dr. Chernyak's assessment here... I'm not a diagnostic radiologist. And in particular for the smaller lesions where some of the findings are more subtle, I'm more reliant on a diagnostic radiologist with relevant expertise to make this determination… If [Dr. Chernyak] classifies it as LI-RADS 3 *and has the appropriate justification*, I have no reason to doubt that."[2] As detailed in Plaintiffs' Motion to Exclude Dr. Chernyak, Dr. Chernyak admitted that the required CT imaging necessary to apply LI-RADS was missing.[3] Furthermore, Dr. Chernyak opines in her expert report that Mr. Roberts' "April 2016 MRI met the criteria for LR-3 and carry ~30% probability of being HCC

[1] Ex. A - Mahmud Dep. 133:3-5, 402:3-23, 403:5-13;
Ex. B - Mahmud Report at 22, 34.
[2] Mahmud Dep. 402:3–403:13 (emphasis added).
[3] 1:20-cv-00946-RMB-SAK Doc 17 filed on 5/22/2025.

in 2016 and a 60% probability of progressing into HCC within 48 months."[4] However, Dr. Chernyak admitted in deposition that Mr. Roberts never underwent a MRI in 2016.[5] Incorrectly claiming that a nonexistant 2016 MRI met the criteria for LR-3 was a material error in Dr. Chernyak's expert report. Additionally, Dr. Chernyak both testified and published regarding the fact that MRIs can give better imaging than a CT and can have a higher specificity in diagnosing cancer than a CT.[6] Dr. Mahmud's LI-RADS-related opinions (that Mr. Roberts had a pre-existing liver lesion that had some potential to have been carcinogenic) are therefore not based on any independent expertise or radiological analysis of his own, but rather rest entirely on the unsupported and inadmissible conclusions of Dr. Chernyak.

Dr. Mahmud testified that in clinical practice, he "will rely on the diagnostic radiologist's read."[7] Dr. Mahmud explained, "Radiologists … have much more dedicated expertise in reviewing radiology than I do. They do it day in and day out as their job."[8] and that he is "differential to the diagnostic radiologist" when interpreting scans.[9]

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[4] Chernyak Report at 9.
[5] Ex. C - Chernyak Dep. 22:17-25:23.
[6] Chernyak Dep. 23:11-24:13, 162:4-13.
[7] Mahmud Dep. 76:1–6.
[8] Mahmud Dep. 80:1–6.
[9] Mahmud Dep. 77:21–78:13.

Despite lacking the radiological expertise, Dr. Mahmud opines in his expert report that based on a 2016 CT, Mr. Roberts' "spleen size is enlarged by my measurements."[10] When asked what the normal spleen size is for an adult male, Dr. Mahmud testified, "So, you know, I'll – I'll state that, you know, in general, I – this is an area of expertise that's more pertinent to a diagnositic radiologist."[11] Dr. Mahmud testified that none of Mr. Roberts' treating physicians diagnosed Mr. Roberts with an enlarged spleen in 2016.[12] Furthermore, Dr. Mahmud admitted that he doesn't diagnose patients with an enlarged spleen in practice, but merely communicates the diagnosis the radiologist makes to the patient.[13] Dr. Mahmud attempted to recover, claiming Dr. Chernyak opined that Mr. Roberts had an enlarged spleen in 2016, but later conceded that Dr. Chernyak gave no such opinion.[14] Dr. Mahmud should be precluded from being able to give opinions based on his intepretation of radiological images.

II. Dr. Mahmud's Tumor Volume Doubling Time Calculation is Unreliable

Dr. Mahmud's testimony regarding tumor volume should be excluded as it is unreliable because A) he made incorrect *assumptions* based on the shape of Mr. Roberts' tumor, B) it was unequivocally proven incorrect by reverse engineering his

[10] Mahmud Report at 22.
[11] Mahmud Dep. 131:13-18.
[12] Mahmud Dep. 135:14-17.
[13] Mahmud Dep. 137:4-138:11.
[14] Mahmud Dep. 138:12-139:17; 304:3-4.

own math, C) he failed to take into account tumor growth rates cited in his own report, D) he did not understand the formula he was applying, and E) he applied a formula not meant to be applied to individual patients.

A. Dr. Mahmud Incorrectly Assumed Mr. Roberts' Cancer was Spherical

Based on the size of Mr. Roberts' liver cancer in August of 2018, Dr. Mahmud used a tumor volume doubling time (TVDT) formula to "back-calculate"[15] the expected size of Mr. Roberts' liver cancer at the time he started NDMA-contaminated valsartan to support the conclusion that "Mr. Roberts almost certainly had undiagnosed HCC at the time of his first exposure to allegedly NDMA contaminated valsartan in September 2016."[16] In order to perform this calculation, Dr. Mahmud had to assume that Mr. Roberts' liver cancer was spherical when it started and remained spherical throughout its progression.[17] Dr. Mahmud explained, "to approximate doubling time, we - we make an assumption that it's a sphere. You know, the formula you have to try to put together to - to accurately get the topography of an HCC mathematically would be, you know, extraordinarily complex."[18] When asked if Mr. Roberts' liver cancer was spherical, Dr. Mahmud replied[19]:

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[15] Dr. Chernyak utilized artificial intelligence (AI) back-calculate the size of Mr. Roberts' liver cancer and came to significantly different results than Dr. Mahmud (Chernyak Report at 8; Chernyak Dep. 199:3-22).
[16] Mahmud Report at 34.
[17] Mahmud Dep. 394:19-25.
[18] Mahmud Dep. 396:16-21.
[19] Mahmud Dep 395:7-24 (emphasis added).

> I – I would have to look at it again in detail. It's sometimes very tough to assess because we – you, oftentimes, may need a good three-dimensional reconstruction of an image, a CT scan or an MRI. You know, we look at it in terms of slices, typically, you know, in a coronal or sagittal or a transverse axis. And, you know, we – I was not presented with any of the three-dimensional reconstructions. So it's – it's **tough for me to be able to say confidently** is it – is it spherical or is it not spherical. **I doubt it's perfectly spherical**.

Instead of relying on the available images to determine the shape of Mr. Roberts' liver cancer, Dr. Mahmud inaccurately assumed that Mr. Roberts' liver cancer was always spherical, so that Dr. Mahmud could "back-calculate" the size of Mr. Roberts' liver cancer to a time before Mr. Roberts was exposed to NDMA-contaminated valsartan. Dr. Mahmud's opinions related to his tumor volume doubling time calculations should be excluded, as they are conclusion-driven and based on inaccurate assumptions.

B. Dr. Mahmud's Calculations Predict Large Tumors at a Time When Multiple Imaging Studies Revealed No Such Tumors

Dr. Mahmud testified that because he believes Mr. Roberts' liver cancer was caused by NASH, that Mr. Roberts' liver cancer would have been slow growing – doubling in volume approximately every 5.3 months.[20] Based on Dr. Mahmud's calculation, Mr. Roberts would have had an approximately 2-centimeter liver tumor when Mr. Roberts underwent a CT on April 18, 2016.[21] However, Mr. Roberts' April

[20] Mahmud Dep. 411:13-15.
[21] Mahmud Report at 34; Mahmud Dep. 399:17-400:6; 413:20-414:4.

2016 CT did not detect anything near that size – the largest observations, which were most likely benign, were approximately half a centimeter.[22] Even Dr. Chernyak (defense expert radiologist) only noted liver observations of approximately half a centimeter in size when she reviewed the April 2016 CT images.[23] Based on his own calculations, Dr. Mahmud should have ruled out NASH as a cause of Mr. Roberts' liver cancer, because liver cancer caused by NASH is slow growing and would have been approximately 2-centimeters in size on Mr. Roberts' 2016 CT and no similarly sized cancer or tumor was present at that time. Instead of ruling out NASH as the cause of Mr. Roberts' liver cancer, Dr. Mahmud insisted that his formula supports his conclusion that Mr. Roberts' had liver cancer prior to ingesting NDMA-contaminated valsartan[24]:

> So, you know, all this is communicating is that it's more likely than not that he already had hepatocellular carcinoma present in the liver when he was first exposed to NDMA. There's going to be variation in what the actual size of the lesions might have been. There's – and, of course, there's error introduced by the assumption of a sphere. So this is not a perfect prediction. But in the plausible ranges of where most patients fit – and in particular patients with NASH or MASH-related cirrhosis, as you've highlighted, where the tumors grow more slowly, he's **almost guaranteed to have already had hepatocellular carcinoma when he was – when he was first exposed to NDMA-contaminated valsartan**.

[22] Mahmud Dep. 400:21-25.
[23] Chernyak Report at 5; Chernyak Dep. 63:5-69:21.
[24] Mahmud Dep. 413:10-414:4 (emphasis added).

Dr. Mahmud's theoretical tumor volume doubling time calculations are unreliable, as they contradict the actual facts of this case and do not "fit" the case. (*See Daubert*, 509 at 592 (the expert testimony must also "fit" the case to be helpful to the trier of fact.)) Dr. Mahmud should be precluded from giving his tumor volume doubling time calculations, as they will only serve to confuse and mislead the jury.

C. Dr. Mahmud Didn't Calculate Projections Counter to His Conclusion

Dr. Mahmud believes that Mr. Roberts' liver cancer had to have been present prior to Mr. Roberts' ingestion of NDMA-contaminated valsartan, because "the fact is ***all*** the projections would predict that he had identifiable lesions on imaging".[25] The fastest tumor volume doubling time that Dr. Mahmud "back-calculated" was 3.9 months, because Dr. Mahmud believed that 3.9 months was the fastest possible time that liver cancer can double in volume.[26] However, the study that Dr. Mahmud cited in his report for tumor volume doubling times notes that liver tumors can double every 2.2 months.[27] Dr. Mahmud conceded he didn't model out Mr. Roberts' liver cancer doubling in size every 2.2 months.[28] Had Dr. Mahmud "back-calculated" Mr. Roberts' liver cancer growth based on a 2.2 month tumor volume doubling time, Mr.

[25] Mahmud Dep. 401:10-12 (emphasis added).
[26] Mahmud Report at 34; Mahmud Dep. 357:1-3, 397:4-7, 398:10-15.
[27] Mahmud Dep. 406:5-14.
[28] Mahmud Dep. 406:25-407:3.

Roberts would not have had cancer prior to ingesting NMDA-contaminated valsartan.[29]

Dr. Mahmud's opinion that Mr. Roberts had to have had liver cancer prior to ingesting NDMA-contaminated valsartan was based on the faulty belief that "***all*** the projections would predict that he had identifiable lesions on imaging."[30] Dr. Mahmud should be precluded from testifying at trial that Mr. Roberts' liver cancer predated his ingestion of NDMA-contaminated valsartan. Additionally, Dr. Mahmud's failure to apply the tumor volume doubling times from the literature he cites to that would give results counter to his ultimate conclusion, is further evidence that Dr. Mahmud's entire expert report is conclusion driven and unreliable.

D. Dr. Mahmud Did Not Understand the Methodology of the Tumor Volume Doubling Time Calculation He Performed

During his deposition, it became clear that Dr. Mahmud did not intimately understand the tumor volume doubling time calculation performed or to what extent it can be applied. Dr. Mahmud testified as follows when questioned how to apply the 2.2-month tumor volume doubling time that was omitted from his expert report[31]:

> Q. And if it was 2.2 months, is the right way to do that, then to be [multiplying] 2.2 by 7 to figure out how many months earlier he would be at based on your calculations?
> A. That does not sound immediately accurate to me. I think you have to really apply this through the formulas that I laid out.

[29] Mahmud Dep. 408:4-11.
[30] Mahmud Dep. 401:10-12 (emphasis added).
[31] Mahmud Dep. 407:6-408:11.

Q. Can you see the expert – can you see – am I back on the expert report screen sharing?
A. Yes.
Q. Okay. Is 3.9 times 7, 27.3? I can screen share a calculator if you need me to.
A. Sure. So it's 3.9 times 7. Yes, that's 27.3.
Q. Okay. And 5.3 times 7, is that 37.1?
A. Yes.
Q. Okay. And so if the tumor volume doubling time was 2.2, would the accurate way to do that be to times it by 7?
A. Yeah. That appears correct based on what you're show me, yes, yes.
Q. Which would be 15 – which would be 15.4 months?
A. Sure, 15.4 months.

Dr. Mahmud was also unsure at what tumor size his tumor volume doubling time calculation would no longer be valid. When asked if his calculation could back-calculate all the way to the inception of the cancer or if his formula stopped being valid for tumors smaller than 1 centimeter, Dr. Mahmud conceded[32]:

> That's a great question. I – you know, **I am not immediately sure**, you know, to what – what I'll say is things are very tough to macroscopically visualize on imaging when they're extremely small. You know, when they're you know, on the range of certainly less than .1 centimeters. Things are very tough to discern when they're extremely, extremely small. So I presume that that could not be modeled accurately in these studies because *you have to be able to measure it on imaging*.

Dr. Mahmud's tumor volume doubling time opinions amount to nothing more than Dr. Mahmud entering cherry-picked data into a formula that will spit out Dr. Mahmud's litigation desired result. Dr. Mahmud does not understand the

[32] Mahmud Dep. 409:6-22 (emphasis added).

methodology or limits of the tumor volume doubling time formula that he applied to conclude that Mr. Roberts' liver cancer must have predated Mr. Roberts' ingestion of NDMA-contaminated valsartan. Dr. Mahmud failing to understand the methodology or limits of the formula he applied amounts to Dr. Mahmud employing an unreliable methodology. As such, Dr. Mahmud should be precluded from offering his tumor volume doubling time opinions.

E. Applying a Tumor Volume Doubling Time Formula to an Individual Patient is Inappropriate, Unreliable and Not Done in Clinical Practice

Tumor volume doubling time formulas are not intended to be applied to individual patients and there is insufficient data to accurately apply such formula to an individual patient. Dr. Chodosh (defense's expert cancer biologist), succinctly explained why it would be unhelpful and unreliable to apply to tumor volume doubling time formula to Mr. Roberts[33]:

> Tumor volume doubling times are generally used across – well, in the clinical setting – clinical research setting or human studies setting, tumor volume doubling time studies are generally studies of multiple individuals with a particular type of cancer at a particular stage that's consistent in attempting to arrive at some kind of estimates, across that population, of what tumor volume doubling time might be. Whereas it's not typically – **not typically something that's done on an individual patient basis. And very commonly it's because there aren't sufficient data** to do that in the great majority of oncology cases. ***Again, nor would it be helpful***.
>
> *****

[33] Ex. D - Chodosh Dep. 86:19-92:20 (emphasis added).

> It's a research metric, **it's not a clinical metric**, at least for the types of solid tumors that I am thinking of right now.
>
> *****
>
> **Cancer growth rates** are a function of time. They are not – even in a patient, they are not necessarily constant, and **almost certainly are not constant**. So it's a function of time. And cancer – even the notion of cancer type is fundamentally dependent on our ability to classify and subclassify cancers, because at some level **every cancer is different based on the mutations that are present and a number of host features**.

Dr. Mahmud's testimony mirrors Dr. Chodosh's testimony on why applying a tumor volume doubling time formula to an individual patient is unreliable[34]:

> So look, these are not guaranteed – guarantees. There's variation within every etiology of liver disease. It's not like every single patient with NASH-related cirrhosis will have a growth rate of 5.3 centimeters. **There's inherent variability based on myriad factors**.

Dr. Mahmud merely applied a generic formula to "back-calculate" the size of Mr. Roberts' liver cancer, without considering or applying any relevant case specifics, such as Mr. Roberts' comorbidities, cancer subclassification, repeated exposure to a mutagen (NDMA), or the mutations involved in Mr. Roberts' liver cancer. Dr. Mahmud's tumor volume doubling formula is unreliable as applied to Mr. Roberts, because the formula does not account for any patient-specific factors, and therefore Dr. Mahmud should be precluded from giving such an opinion at trial.

[34] Mahmud Dep. 413:2-9.

III. Mr. Roberts Was Never Diagnosed with NASH and Dr. Mahmud Does Not Have a Reliable Basis to Diagnose Mr. Roberts with NASH

It is Dr. Mahmud's opinion that Mr. Roberts' liver cancer was caused by nonalcoholic steatohepatitis (NASH), also known as metabolic dysfunction-associated steatohepatitis (MASH).[35] NASH is the more severe form of nonalcoholic fatty liver disease (NAFLD), also known as metabolic dysfunction-associated steatotic liver disease (MASLD).[36] Dr. Mahmud explained that approximately one in three individuals in the United States have NAFLD and only a subset of patients with NAFLD go on to develop NASH.[37] NAFLD merely means that a person has fat in their liver, therefore "most people who are obese likely have NAFLD".[38] NALFD (a fatty liver) "generally does not cause symptoms."[39] NASH on the other hand is fat plus inflammation in the liver that typically causes symptoms, including weakness, loss of appetite, nausea, yellow skin and eyes, itching, fluid buildup, swelling of the legs and abdomen, mental confusion, and GI bleeding.[40] Dr. Mahmud admitted that Mr. Roberts did not have any symptoms associated with NASH.[41] Furthermore, Dr. Mahmud explained that NASH is "technically a

[35] Mahmud Dep. 411:22-24, 152:9-10.
[36] Mahmud Dep. 149:10-153:4, 159:14-19.
[37] Mahmud Dep. 184:21-185:18.
[38] Mahmud Dep. 186:12-19.
[39] Mahmud Dep. 151:11-16.
[40] Mahmud Dep. 152:17-154:17, 164:15-22.
[41] Mahmud Dep. 154:7-155:13.

pathological diagnosis" and that you need a liver biopsy to confirm a diagnosis of NASH instead of NAFLD.[42] Therefore, a diagnosis of NASH is outside the scope of Dr. Mahmud's expertise, as Dr. Mahmud is not a pathologist. Even if Dr. Mahmud was qualified to make a pathological diagnosis, a liver biopsy was never conducted on Mr. Roberts prior to his cancer diagnosis.[43]

Because Mr. Roberts was never diagnosed with NASH, showed no symptoms of NASH, and never underwent a biopsy necessary to diagnose NASH, Dr. Mahmud's assertion that NASH caused Mr. Roberts' liver cancer is speculative and lacks foundation. Expert opinions must be grounded in reality and based on reliable methodology; Dr. Mahmud is just asserting a conclusion. The Court should preclude Dr. Mahmud from opining that Mr. Roberts had NASH.

IV. Dr. Mahmud's Reliance on His FIB-4 Score Calculation to Diagnose Mr. Roberts with NASH, Cirrhosis, or Advanced Liver Fibrosis is Unreliable

Dr. Mahmud's opinions based on his FIB-4 calculation should be excluded as unreliable because 1) FIB-4 scores are not diagnostic, B) he does not understand FIB-4 and therefore applied it incorrectly, C) admitted that Mr. Robert's age makes FIB-4 unreliable, D) applied his own diagnosis of low platelet count, contrary to both treating doctors and objective labs, and did not consider alternate causes.

[42] Mahmud Dep. 159:14-160:5.
[43] Mahmud Dep. 161:10-13, 164:15-165:6.

A. FIB-4 Scores Are Not Diagnostic

Even though Dr. Mahmud lacked the required biopsy necessary to diagnose Mr. Roberts with NASH, Dr. Mahmud believed he could *infer* that Mr. Roberts had NASH based on a FIB-4 score that Dr. Mahmud calculated.[44] Dr. Mahmud agreed that his employer's website, Penn Medical, lists the ways to diagnosis NASH and that a FIB-4 score is not among that list.[45] Dr. Mahmud explained that the American College of Gastroenterology guidelines "now includes FIB-4 scores in the diagnostic *algorithm* to identify patients who *may* have cirrhosis or need further evaluation", but FIB-4 scores themselves are not diagnostic.[46] When pushed further on whether he could diagnose cirrhosis with a FIB-4 score, Dr. Mahmud conceded, "Not – not – not in and of itself to diagnose cirrhosis, but as a tool to risk stratify – risk stratify patients with chronic liver disease who may require further testing to --- to rule in or rule out cirrhosis."[47] Dr. Mahmud should be precluded from using a non-diagnostic FIB-4 score to diagnose Mr. Roberts with NASH or cirrhosis.

B. Dr. Mahmud Did Not Know the Methodology of the FIB-4 Calculation, Resulting in Repeated Misapplication

Dr. Mahmud explained that the FIB-4 formula is a "relatively new" methodology developed a couple of years ago by a Dr. Richard Sterling, who

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[44] Mahmud Dep. 160:17-20.
[45] Mahmud Dep. 160:21-24.
[46] Mahmud Dep. 197:8-198:9.
[47] Mahmud Dep. 192:25-193:12.

selected "labs that were *plausibly* related to cirrhosis."[48] When asked if he knew how the FIB-4 score was developed, Dr. Mahmud gave the following answers[49]:

> I would have to find the seminal studies to look at the methodology in detail.
>
> *****
>
> And so the score – the formula that's used for this has a ratio of AST and ALT, and then it has platelets as a factor. ***I think it's multiplied by that. The square root is in the formula somewhere***, and then age factors in.
>
> *****
>
> That's the general methodology that – that I, you know, I think was used in this case.

It is clear that Dr. Mahmud did not know the FIB-4 formula, which is likely why he did not include the FIB-4 formula anywhere in his expert report.[50] Instead of familiarizing himself with the FIB-4 formula that is the basis to his expert opinion, Dr. Mahmud just entered numbers into MDCalc.com, which Dr. Mahmud describes as a "repository for lots of prediction scores."[51] Dr. Mahmud was not sure what organization maintains MDCalc.com, but believes whatever company it is reaches out to the inventors of a formula to get their permission to put a formula on their website.[52] Dr. Mahmud also testified that the company that maintains MDCalc.com

[48] Mahmud Dep. 197:8-20, 198:14-15, 201:23-202:10 (emphasis added).
[49] Mahmud Dep. 201:9-14, 203:3-8, 204:8-16.
[50] Mahmud Dep. 96:8; Mahmud Report.
[51] Mahmud Dep. 212:22-213:12, 223:16-24.
[52] Mahmud Dep. 214:22-215:13.

identifies scores that have been well-studied and validated.[53] However, as an expert, it is necessary for Dr. Mahmud to verify that the formula he is applying has been well-studied, validated, and appropriate for the individual patient he is applying it to – none of which Dr. Mahmud did.

As a result of not knowing the methodology behind the FIB-4 calculation, Dr. Mahmud did not convert the FIB-4 score to the schema for classifying fibrosis that the FIB-4 was developed to correlate with. Dr. Mahmud testified as follows when confronted with his methodology differing from the methodology of the inventor of the FIB-4 score[54]:

> Yeah. So they – they – it looks like they use a different schema for classifying fibrosis. There's – I've been referring to something called METAVIR staging, which goes from 0 to 4. It looks like what he's using is something called Ishak framework, which ranges from 0 to 6, but it's the same principle that there's progressive fibrosis that you can break into, you know, stages of fibrosis.

Furthermore, Dr. Mahmud was unaware of the patient population that the FIB-4 score was developed from, even though it is prominently displayed on the website that he used to calculate the FIB-4 score in this case, as evidenced by the following testimony[55]:

> Q. And do you see up here at the top where it says, "FIB-4 was developed in patients with HIV and HCV [Hep C] coinfections"?
> A. Yes, I see that.

[53] Mahmud Dep. 215:5-6.
[54] Mahmud Dep. 220:2-11.
[55] Mahmud Dep. 216:7-19.

Q. And does that mean that the patients that FIB-4 was developed on had both HIV and HCV?
A. That – yeah. That appears to be the case based on that sentence.
Q. Is that what "coinfection" means, you have both infections at the same time?
A. Yeah. That typically means you have both infections.

Dr. Mahmud conceded that he applied the FIB-4 calculation to Mr. Roberts even though Mr. Roberts did not have HIV, AIDS, or HCV (hepatitis C).[56]

Dr. Mahmud was unaware of the FIB-4 methodology and instead relied on a website to perform the calculation, resulting in Dr. Mahmud misapplying the FIB-4 calculation multiple times. Dr. Mahmud should be precluded from calculating a FIB-4 score for Mr. Roberts, because Dr. Mahmud does not understand the FIB-4 methodology or apply it as intended.

C. Age as a Factor Makes FIB-4 Unreliable as Applied to Mr. Roberts

Dr. Sterling, the creator for the FIB-4 calculation cautions users about the perils and pitfalls of using a FIB-4 calculation, specifically that FIB-4 "was developed in a cohort of subjects that did not include the young or very old, so it might not perform as well in those populations, given that the age is the numerator. Furthermore, inclusion of age makes it less reliable to use longitudinally."[57] In response to Dr. Sterling's caution, Dr. Mahmud testified, "So I – I don't know necessarily the full context of what he refers to there… perhaps his perception is that

[56] Mahmud Dep. 218:8-12.
[57] Mahmud Dep. 218:13-219:1.

[age] impacts the reliability of it."[58] Dr. Mahmud was then asked if it was because age alone could make ones' FIB-4 score abnormal, and responded[59]:

> Yes. I think I stated that previously that, you know, someone who is very old, just on – on – you know, **on the basis of age alone, they can have an elevated FIB-4**.

Dr. Mahmud also testified that when "age is the driving factor for a FIB-4 being elevated. My suspicion is that it's a little bit less accurate in that setting."[60]

Dr. Mahmud testified that he believed Mr. Roberts had elevated liver levels (AST and ALT) since he was a teenager, and that elevated AST and ALT levels don't necessarily cause liver inflammation.[61] Dr. Mahmud then agreed that if Mr. Roberts had the exact same labs when he was a teenager, his FIB-4 score would have been normal – excluding the possibility of advanced fibrosis or cirrhosis.[62] Dr. Mahmud was then asked[63]:

> Q. So strictly his age is what is giving that result of fibrosis on the FIB-4 score?
>
> A. Well, yes.

A FIB-4 score is unreliable as applied to Mr. Roberts, because the score is abnormal strictly as a function of Mr. Roberts' age. In essence, Dr. Mahmud is

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[58] Mahmud Dep. 219:2-11.
[59] Mahmud Dep. 219:12-18.
[60] Mahmud Dep. 212:11-14.
[61] Mahmud Dep. 230:5-11.
[62] Mahmud Dep. 231:12-21.
[63] Mahmud Dep. 231:20-232:1.

opining that Mr. Roberts got cancer because he is old (60 years old when first exposed to NDMA-contaminated valsartan), and is using a FIB-4 score to disguise and bolster that opinion. Because Mr. Roberts' FIB-4 score was abnormal strictly as a function of his age, Dr. Mahmud should be precluded from mentioning the FIB-4 score that he calculated.

D. Platelets as a Factor Makes FIB-4 Unreliable as Applied to Mr. Roberts

Other than age, AST and ALT (both of which had been mildly elevated since Mr. Roberts was a teenager), the FIB-4 score only considers platelet count.[64] As such, Dr. Mahmud considered Mr. Roberts' platelet counts to be the most important lab finding.[65] Dr. Mahmud agreed that the platelet count makes a big determination in the final value of a FIB-4 score and that it's very important to investigate any causes that might drop or increase someone's platelet count.[66] As detailed below, Dr. Mahmud failed to consider numerous likely explanations for Mr. Roberts' varying platelet counts.

1. Dr. Mahmud Ignores Laboratory Reference Ranges for Normal Results

Dr. Mahmud agreed that low platelets (thrombocytopenia) would be flagged as an abnormal CBC (Complete Blood Count) result.[67] When asked how to

[64] Mahmud Dep. 202:10.
[65] Mahmud Dep. 95:22-96:1, 202:18.
[66] Mahmud Dep. 209:24-210:6.
[67] Mahmud Dep. 192:3-5.

determine if a lab is out of range, Dr. Mahmud explained, "generally a normal range is reported by – by a particular lab, and ***that may vary based on the particular lab where it's obtained***."[68] Despite this, Dr. Mahmud diagnosed Mr. Roberts with thrombocytopenia (low platelets) on November 4, 2015, based on a platelet count of 137, even though the reporting laboratory's normal low end reference range was 130, Mr. Roberts' CBC was normal, and none of Mr. Roberts' treating physicians diagnosed him as thrombocytopenic.[69] Dr. Mahmud testified that he was aware that the labs low end of normal reference range was 130 even though he didn't mention it in his expert report.[70] Dr. Mahmud should be precluded from opining that Mr. Roberts had low platelets at times when Mr. Roberts' platelets were within the testing laboratories' normal reference ranges. Additionally, Dr. Mahmud's knowledge that Mr. Roberts' platelets were within the testing laboratory's normal range, and Dr. Mahmud's failure to include such information in his expert report, further demonstrates that Dr. Mahmud's entire expert report is conclusion driven.

Dr. Mahmud then applied Mr. Roberts' "low platelet" result to calculate a FIB-4 score that Dr. Mahmud claims indicates that Mr. Roberts likely had advanced liver fibrosis or cirrhosis as of November 4, 2015.[71] However, the platelet count entered

[68] Mahmud Dep. 98:23-99:3.
[69] Mahmud Dep. 242:22-244:8.
[70] Mahmud Dep. 244:14-23.
[71] Mahmud Report at 7.

into the FIB-4 score is supposed to be based on laboratory results that have a normal low end platelet range of 150. Dr. Mahmud did not convert what a platelet count of 137 with a normal low-end platelet range of 130 would be if the laboratory's normal low-end platelet range was 150.[72] Dr. Mahmud should be precluded from calculating a FIB-4 score for Mr. Roberts, because Dr. Mahmud ignored laboratory reference ranges and failed to account for any differences.

2. Dr. Mahmud Did Not Consider Other Causes for Platelet Variation

When asked limitations of the FIB-4 index, Dr. Mahmud explained that you must interpret it in the context of what is happening with the individual patient and gave the example, "sometimes the platelet count can be invalidated in some patients where it no longer becomes a good proxy for portal hypertension and – and liver disease and cirrhosis."[73] Therefore, Dr. Mahmud agreed that it is very important to investigate any causes that might drop or increase someone's platelet count.[74] Dr. Mahmud testified, "I think very carefully about the platelet count in particular because I know that you have to be mindful of interpreting that in the context when you compute a FIB-4."[75] However, Dr. Mahmud did not do any research to see if

[72] Mahmud Dep. 242:22-243:3, Mahmud Report at 7.
[73] Mahmud Dep. 207:24-208:23.
[74] Mahmud Dep. 210:3-6.
[75] Mahmud Dep. 248:1-5.

Mr. Roberts had been started on any medications that could have explained his platelet drop.[76]

a. Dr. Mahmud Did Not Consider Proton Pump Inhibitors (PPIs) as a Cause of Mr. Roberts' "Low Platelets"

Dr. Mahmud noted in his expert report that Mr. Roberts' platelets were normal, that Mr. Roberts was later started on a Proton Pump Inhibitor (PPI), and then Mr. Roberts' developed low platelets on November 4, 2015 (low platelets per Dr. Mahmud's definition – not per the laboratory or Mr. Roberts' treaters).[77] Even though Dr. Mahmud made note of Mr. Roberts starting a PPI in his report, Dr. Mahmud testified that PPIs are of no relevance to his opinion and he didn't conduct any research on PPIs causing low platelets.[78] Dr. Mahmud was unaware that literature existed, including case reports and a retrospective study, demonstrating that PPIs can cause thrombocytopenia.[79]

b. Dr. Mahmud Did Not Consider Hydrochlorothiazide (HCTZ) as a Cause of Mr. Roberts' "Low Platelets"

Dr. Mahmud testified that he believed it was possible for diuretics to cause a decrease in platelets, but that he was unsure which diuretics could cause a decrease in platelets, and that he didn't do any research on diuretics causing a decrease in

[76] Mahmud Dep. 249:19-23.
[77] Mahmud Dep. 239:20-243:3; Mahmud Report at 7.
[78] Mahmud Dep. 241:14-22, 259:14-21, 268:18-21.
[79] Mahmud Dep. 256:14-257:16, 267:16-268:21.

platelets.[80] A couple of weeks before Dr. Mahmud claims Mr. Roberts had "low platelets", Mr. Roberts was transitioned from valsartan to valsartan HCTZ.[81] The HCTZ of valsartan HCTZ stands for hydrochlorothiazide, which is a diuretic.[82] Dr. Mahmud agreed that Mr. Roberts' platelets started decreasing several days after starting valsartan HCTZ.[83] Even though Mr. Roberts' valsartan HCTZ was started just weeks before Mr. Roberts first "low platelet count", Dr. Mahmud didn't conduct any research into the possibility of HCTZ, a diuretic, causing lower platelet counts.[84] When confronted with peer-reviewed literature, Dr. Mahmud conceded that thiazide diuretics, such as HCTZ, have been found to induce thrombocytopenia in approximately 25% of patients.[85]

c. Dr. Mahmud Did Not Consider NDMA as a Cause of Mr. Roberts' "Low Platelets"

Dr. Mahmud agrees that the first time Mr. Roberts' platelets were low per a laboratory's reference range, or considered low by his treating physicians, was on October 27, 2016.[86] Dr. Mahmud notes in his report that Mr. Roberts was started on NDMA-contaminated valsartan on September 19, 2016, approximately 1 month

[80] Mahmud Dep. 278:1-10, 281:8-12.
[81] Mahmud Dep. 280:19-281:1.
[82] Mahmud Dep. 281:2-7.
[83] Mahmud Dep. 284:14-22.
[84] Mahmud Dep. 281:8-12.
[85] Mahmud Dep. 283:19-284:6.
[86] Mahmud Dep. 291:18-21, 322:3-6, 322:11-323:4, 323:20-324:1.

before Mr. Roberts actually developed thrombocytopenia.[87] Dr. Mahmud did not consider, much less rule out, NDMA as a cause of Mr. Roberts' thrombocytopenia, even though the United States Health and Human Services reported in 2023 instances of NDMA exposure causing thrombocytopenia in humans.[88]

d. NDMA and HCTZ in Mr. Roberts' Valsartan Were the Most Likely Causes of Mr. Roberts' Temporarily Decreased Platelet Count

Dr. Mahmud agreed that a "de-challenge", which is when an exposure is removed and the side effect goes away, is strong causal evidence.[89] Upon reviewing Mr. Roberts' pharmacy records, Dr. Mahmud agreed that Mr. Roberts filled his last NDMA-contaminated valsartan HCTZ prescription on June 15, 2018, making Mr. Roberts' last dose of NDMA-contaminated valsartan HCTZ around the middle of September 2018.[90] Furthermore, Dr. Mahmud agreed that after discontinuing NDMA-contaminated valsartan HCTZ, Mr. Roberts' platelets went back up in his next CBC on December 3, 2018, even though Mr. Roberts had been diagnosed with liver cancer months earlier.[91] Mr. Roberts' platelets rebounded once he was no longer exposed to NDMA-contaminated valsartan HCTZ, which is known as a "de-challenge" and is strong causal evidence. Dr. Mahmud should be precluded from

[87] Mahmud Report at 8; Mahmud Dep. 291:14-21.
[88] Mahmud Dep. 361:19-362:4.
[89] Mahmud Dep. 263:2-5, 284:24-285:14.
[90] Mahmud Dep. 335:22-336:10.
[91] Mahmud Dep. 327:1-328:6, 336:11-14.

opining on the causes of Mr. Roberts' platelet counts, because Dr. Mahmud didn't consider the most likely causes of Mr. Roberts' varying platelet counts. Dr. Mahmud's lack of investigation into whether the very substance alleged to have caused Mr. Roberts' liver cancer, NDMA-contaminated valsartan HCTZ, could have also explained Mr. Roberts' varying platelet counts, is clear evidence of a conclusion driven expert report.

V. Dr. Mahmud Can Not Reliably Opine that Mr. Roberts had Cirrhosis, Because Dr. Mahmud Bases That Opinion on His Unreliable FIB-4 Calculation and Mr. Roberts' "Low Platelets"

Dr. Mahmud explained that cirrhosis is a state in which there is a significant amount of scarring (fibrosis) in the liver that accumulates to the point where the fibrosis affects the liver's function.[92] Importantly, Dr. Mahmud also clarified that a patient can have advanced liver fibrosis and not have cirrhosis.[93] Furthermore, Dr. Mahmud explained that most radiologists just use the term "cirrhosis" instead of "advanced fibrosis", because radiologists are just looking at the signs that are observed on imaging.[94] Dr. Mahmud agreed that for the sake of communicating with a lay person, cirrhosis is scarring of the liver ***and*** poor liver function.[95] Dr. Mahmud

[92] Mahmud Dep. 108:16-24, 112:7-8.
[93] Mahmud Dep. 112:17-19.
[94] Mahmud Dep. 114:4-13.
[95] Mahmud Dep. 123:13-124:7.

does not dispute that Mr. Roberts was not diagnosed with cirrhosis prior to being diagnosed with cancer in 2018.[96]

Dr. Mahmud explained that cirrhosis is usually defined and diagnosed based on a liver biopsy.[97] Mr. Roberts never underwent a liver biopsy necessary to diagnose Mr. Roberts with cirrhosis.[98] Furthermore, Dr. Mahmud agreed that Mr. Roberts did not have any symptoms consistent with cirrhosis, such as weight loss, fatigue, or telangiectasias (dilated blood vessels appearing as red spider-like patterns on the skin).[99] Despite lacking the necessary biopsy, a clinical diagnosis, or any supporting symptomatology, Dr. Mahmud plans to tell the jury that Mr. Roberts had cirrhosis years before his cancer diagnosis, based solely on predictive modeling and subjective interpretation.[100] Dr. Mahmud can not reliably opine that Mr. Roberts had cirrhosis prior to ingesting NDMA-contaminated valsartan and should be precluded from giving such opinion at trial.

A. Dr. Mahmud Did Not Consider NDMA as a Cause of Mr. Roberts' Alleged Cirrhosis

Dr. Mahmud opined in his report that "there is no scientific evidence" that "NDMA is a cause of cirrhosis".[101] In deposition, Dr. Mahmud clarified that there

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[96] Mahmud Dep. 298:12-20, 311:6-10.
[97] Mahmud Dep. 110:5-17.
[98] Mahmud Dep. 161:10-13.
[99] Mahmud Dep. 127:6–129:8.
[100] Mahmud Dep. 130:6–23.
[101] Mahmud Report at 20; Mahmud Dep. 358:11-23.

was existing literature demonstrating NDMA can cause cirrhosis, but that he didn't believe the existing literature was of "sufficient quality" for him to make a causal link that NDMA could cause cirrhosis in humans.[102] Dr. Mahmud was then confronted with statements from the United States Health and Human Services detailing how two researchers got liver cirrhosis after exposure to NDMA in a laboratory setting.[103] Rather than reconsidering his opinion in light of this reliable scientific evidence that NDMA can cause cirrhosis in humas, Dr. Mahmud dismissed it as irrelevant, asserting that "it's very clear that he already has cirrhosis at the time he's first exposed. So obviously, the NDMA could not have been the cause."[104] Again, Dr. Mahmud's opinions are unsupported, conclusion and litigation driven - NDMA couldn't have caused Mr. Roberts' liver cancer because he must have already had liver cancer; NDMA couldn't have caused Mr. Roberts' cirrhosis because he must have already had cirrhosis. Dr. Mahmud should be precluded from opining as to the cause of Mr. Roberts' alleged cirrhosis.

VI. Dr. Mahmud Has No Reliable Basis to Opine that Mr. Roberts' Alleged Liver Cirrhosis Decreased the Carcinogenic Risk Posed by the NDMA-Contaminated Valsartan Mr. Roberts Consumed

Dr. Mahmud gave additional specific causation opinions during his deposition that were not expressed in his expert report. While testifying, Dr. Mahmud found it

[102] Mahmud Dep. 363:23-364:10.
[103] Mahmud Dep. 365:23-366:3.
[104] Mahmud Dep. 367:12–16.

necessary "to emphasize that **all the animal studies study animals that have normal livers at baseline**. They're exposing normal healthy, you know, rodents or whatever animal model they're using. They have a healthy liver."[105] Dr. Mahmud then opined for the first time, "if you have cirrhosis, your liver is not healthy. You do not have normal metabolic activity. We don't even know if a – if a cirrhotic liver could actually metabolize NDMA to those reactive intermediaries. So that's one important point."[106] Dr. Mahmud confirmed that it was his opinion that someone with liver disease (cirrhosis) would be at a *decreased* risk from NDMA exposure – "yes, it's very plausible that a patient with cirrhosis would actually be relatively protected from you know, NDMA related toxicity".[107]

Dr. Mahmud conceded that he did not have any scientific evidence to support his declaration that someone with pre-existing liver cirrhosis/ disease would be at a decreased risk of liver cancer from NDMA exposure.[108] While there is absolutely no scientific evidence to support Dr. Mahmud's assertion that Mr. Roberts would have been at a decreased risk of liver cancer from NDMA ingestion if he had cirrhosis, there is strong scientific evidence that the exact opposite is true – Mr. Roberts would have been more susceptible to NDMA if he had cirrhosis or a

[105] Mahmud Dep. 372:2-7 (additional emphasis added).
[106] Mahmud Dep. 385:2-9.
[107] Mahmud Dep. 387:20-388:5, 390:7-11.
[108] Mahmud Dep. 390:13-20.

weakened liver. In April 2023, the U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry (ATSDR) published a 231-page Toxicological Profile for N-Nitrosodimethylamine (NDMA). Dr. Mahmud agrees that the U.S. Department of Health and Human Services warns, "Other Factors Influencing Susceptibility – Because the liver is the primary target of NDMA toxicity, individuals with liver disease may be at increased risk from NDMA exposure."[109]

VII. Dr. Mahmud Can Not Reliably Opine as to the Cause of Mr. Roberts' Liver Cancer

Dr. Mahmud plans to tell the jury that Mr. Roberts was "almost guaranteed to have already had hepatocellular carcinoma when he was – when he was first exposed to NDMA-contaminated valsartan".[110] However, there is no evidence in the record to support the contention that Mr. Roberts had cancer in 2016. In fact, numerous imaging studies conducted right before Mr. Roberts began taking NDMA-contaminated valsartan demonstrate that Mr. Roberts did not have cancer prior to taking NDMA-contaminated valsartan. Even Dr. Chernyak (defense's expert radiologist), cannot say to any reasonable degree of medical certainty that Mr. Roberts had cancer in 2016.[111]

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[109] Mahmud Dep. 391:14-24.
[110] Mahmud Dep. 414:1–4.
[111] Chernyak Dep. 82:22-83:6, 148:7-149:15.

Dr. Mahmud opines in his expert report that Mr. Robert's liver cancer was a direct result of his longstanding NASH (MASH).[112] However, as detailed above, Mr. Roberts was never diagnosed with NASH and Dr. Mahmud had no reliable basis to diagnose Mr. Roberts with NASH, much less longstanding NASH. Most importantly, Dr. Mahmud did not properly consider Mr. Roberts' NDMA exposure as a potential cause for his liver cancer, because Dr. Mahmud had already baselessly concluded that Mr. Roberts had liver cancer prior to ingesting NDMA-contaminated valsartan, and incorrectly assumed that Mr. Roberts' weakened liver would make Mr. Roberts less susceptible to the carcinogenic effects of NDMA, when all scientific evidence indicates that Mr. Roberts would have been even more susceptible to the carcinogenic effects of NDMA.

Dr. Mahmud conceded that the amount of NDMA that Mr. Roberts is alleged to have been exposed to would have been "a high dose every single day for as long as he was prescribed valsartan".[113] However, because Dr. Mahmud thought it was almost guaranteed Mr. Roberts had liver cancer prior to ingesting NDMA-contaminated valsartan, it did not matter to Dr. Mahmud how much NDMA Mr. Roberts was exposed to – "My opinion does not actually change depending on even if he was exposed to a higher dose" because there's "no plausible way you can say

[112] Mahmud Report at 41; Mahmud Dep. 411:22-412:3.
[113] Mahmud Dep. 64:4-6.

that NDMA, regardless of the dose, could have caused it if it's already there.[114] Dr. Mahmud did not properly consider the very substance that Plaintiffs allege caused Mr. Roberts' liver cancer. Dr. Mahmud should be precluded from asserting his baseless conclusion that Mr. Roberts must have had liver cancer prior to ingesting NDMA-contaminated valsartan at trial.

CONCLUSION

For these reasons, the Court should exclude Dr. Mahmud from testifying at trial.

Respectfully submitted,

By*: /s/ C. Brett Vaughn*

C. Brett Vaughn, RN, BSN, JD
NIGH GOLDENBERG RASO & VAUGHN, PLLC
Attorneys for Plaintiffs
14 Ridge Square NW
Third Floor
Washington, D.C. 20016
Tel: 202-792-7927
Fax: 202-792-7927
Email: bvaughn@nighgoldenberg.com

[114] Mahmud Dep. 352:25-355:17.

CERTIFICATE OF SERVICE

I hereby certify that on May 22, 2025, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notifications of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ C. Brett Vaughn

C. Brett Vaughn, RN, BSN, JD